Attachment 4 DEC 1 7 2001 K013972

510(k) Summary

Device Description	Trade Name:	H/S Elliptosphere Catheter Set
	Common Name:	Hysterosalpingography or Hysterosonography Catheter
	Classification Name:	Cannula, manipulator/injector, Uterine, Product Code LKF
Predicate Device	Modified Hysterosalpingography Set with Polyurethane Balloon K961752, 8/19/96	
Date	November 26, 2001	
Contact	Richard Hettenbach Vice President, Regulatory Affairs and Quality Assurance Ackrad Laboratories, Inc. 70 Jackson Drive Cranford, NJ 07016 Tel: (908) 276-6390 Fax: (908) 276-1895	
Device Description	The H/S Elliptosphere Catheter Set can be used for conducting either Hysterosalpingography (examination of the uterus and fallopian tubes using x-rays) or Hysterosonography (examination of the uterus and fallopian tubes using ultrasound sonography). All components are provided sterile for single use only.	
Technological Characteristics	The H/S Elliptosphere Catheter Set has the same technological characteristics as the predicate device. The intended use, operating principle are identical. The H/S Elliptosphere Catheter Set incorporates the same product design and is packaged and sterilized using the same materials and processes.	

Performance Data	Pre-clinical testing has been conducted to verify that the product meets the performance requirements described. It was determined that the H/S Elliptosphere Catheter Set performs safely and effectively.
Conclusion	The H/S Elliptosphere Catheter Set is substantially equivalent to the predicate Modified Hysterosalpingography Set with Polyurethane Balloon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 7 2001

Mr. Richard Hettenbach
Vice President, Regulatory
Affairs and Quality Assurance
Ackrad Laboratories
70 Jackson Drive
P.O. Box 1085
CRANFORD NJ 07016

Re: K013972
Trade/Device Name: H/S Elliptosphere Catheter Set
Model 61-4005
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 LKF
Dated: November 26, 2001
Received: December 3, 2001

Dear Mr. Hettenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number K013972

Device Name H/S Elliptosphere Catheter Set

Indications for Use The H/S Elliptosphere Catheter Set is used for the delivery of diagnostic contrast media agents in the female reproductive tract for examination of the uterus and fallopian tubes.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013972